UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

UNITED STATES OF AMERICA and THE STATES OF CALIFORNIA and ILLINOIS, EX REL. SCARLETT LUTZ and KAYLA WEBSTER, *Plaintiffs/Relators*, v. LABORATORY CORPORATION OF AMERICA HOLDINGS, *Defendant*.	CA No.: 9:14-cv-3699-RMG

MEMORANDUM OF LAW IN SUPPORT OF LABORATORY CORPORATION OF AMERICA HOLDINGS' MOTION TO DISMISS FOURTH AMENDED QUI TAM COMPLAINT

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INTRODUCTION

A company typically does not report a fraud to the government for which it would *itself* be liable. Yet that implausible scenario is exactly what Relators imagine happened here with Defendant Laboratory Corporation of America Holdings ("LabCorp"). LabCorp—a provider of clinical laboratory services—alerted the government multiple times about possible improper payments made to doctors by its competitors Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"). LabCorp's efforts ultimately elicited a Fraud Alert from the Department of Health and Human Services Office of Inspector General ("OIG"). *See* Department of Health and Human Services Office of Inspector General, Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014).[1] But Relators now have the audacity to allege that LabCorp was actually complicit in the scheme all along.

Relators specifically seek to punish LabCorp for practices that help LabCorp patients whose doctors have ordered blood tests from multiple labs. In such circumstances, the patient often would need to have blood drawn separately, possibly in different locations, for each lab's tests. A LabCorp phlebotomist could, however, draw both blood specimens (with the additional blood draw known as a "courtesy draw")—thus sparing the patient an extra needle. In addition, LabCorp will sometimes place phlebotomists in doctors' offices to service LabCorp patients, as the government has made clear is perfectly legal.

According to Relators, however, LabCorp's good-faith, patient-minded practices are purportedly the basis for False Claims Act ("FCA") liability, largely on a theory of guilt by association. In their Fourth Amended Complaint ("Complaint"), Relators detail at length the improper HDL and Singulex payments that LabCorp reported to the government. Relators then

[1] Available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/oig_sfa_laboratory_payments_06252014.pdf.

allege that LabCorp courtesy draws sometimes involved patients whose doctors had received such payments and ordered tests from HDL or Singulex. And Relators then seek to make the leap that, as a result of sometimes drawing blood that doctors sent to HDL or Singulex, LabCorp should somehow be held liable for having "caused" those companies' resulting false claims for government payment, and that LabCorp should be treated as equally culpable.

Relators also allege that the LabCorp in-office phlebotomists ("IOPs") *themselves* constituted kickbacks that taint all of LabCorp's own claims—even though the federal government has long recognized that IOPs are appropriate. *See, e.g.*, Department of Health and Human Services Office of Inspector General, Special Fraud Alert: Provision of Phlebotomy Services to Physicians (Dec. 19, 1994) ("When permitted by State law, a laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory.") ("1994 OIG Guidance").[2] In addition, Relators allege that LabCorp is somehow responsible for doctors' medical necessity determinations regarding what tests to order. LabCorp ran the tests that the doctors ordered, but Relators nonetheless try to fashion this as an additional basis of FCA liability for tests that Relators now contend were medically unnecessary (specifically because they overlapped or duplicated tests the doctors also ordered from HDL or Singulex).

LabCorp denies all liability and takes offense at Relators' attempt to paint longstanding, routine industry practices as symptoms of some enormous fraud. The government investigated these allegations and declined to intervene, and LabCorp looks forward to refuting Relators' allegations at the appropriate time. For now, however, recognizing that it must generally accept

[2] Available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

the allegations as true, LabCorp moves to dismiss the numerous claims that are ripe for dismissal on the pleadings.

First, the Complaint does not state a claim against LabCorp for submitting claims for medically unnecessary tests, which is Relators' only theory that does not involve the purported payment of kickbacks (whether by HDL, Singulex, or LabCorp). As courts and the government have noted, a lab like LabCorp can rely on a doctor's medical judgment about what tests are medically necessary. This fundamental principle requires dismissal of Relators' non-kickback claims across all four Counts.

Second, the Complaint does not state a claim against LabCorp for reverse false claims liability, as alleged in Count II. This cause of action requires LabCorp to have wrongfully avoided an obligation to pay the government. Relators allege no such obligation and instead contend simply that LabCorp should have repaid money received through the purported false claims that are already the subject of Count I. This Court and others have routinely rejected allegations like these, under which reverse false claims liability would be redundant of liability for submission of the false claims in the first place. *See, e.g., United States v. Berkeley Heartlab, Inc.*, 247 F. Supp. 3d 724, 733 (D.S.C. 2017). Separately, Relators' reverse false claims allegations fail Rule 9(b) as well.

Third, Relators lack standing to pursue their two claims under California law (Count III) and Illinois law (Count IV). Relators seek to impose liability under state statutes that are like the FCA, but that concern claims submitted to private insurers (not the government) and that confer standing only upon "interested persons" (not all citizens). Relators do not allege any cognizable interest in purported insurance fraud in California and Illinois; all they cite is their interest in receiving a share of the recovery, which is plainly not enough. Moreover, these claims also fail

Rule 9(b), because the Complaint provides no details about any claims submitted to private insurers in California and Illinois, or about any private insurance policies that were supposedly breached.

Finally, Relators' conspiracy theory should be rejected out of hand. The Complaint does not allege any agreement between LabCorp and its competitors HDL and Singulex, as conspiracy liability requires. That omission makes sense, of course, given that LabCorp—rather than conspiring with them—reported both companies' activities to the government.

STATEMENT OF FACTS

I. THE PARTIES

LabCorp is a publicly traded Delaware corporation based in Burlington, North Carolina. FAC ¶ 58. LabCorp is one of the largest providers of clinical laboratory services in the United States. *Id.* ¶ 59. It services hundreds of thousands of clients (including patients, doctors' offices, and hospitals) and tests millions of specimens each year. *See* https://www.labcorp.com/about-us (last visited Oct. 10, 2018).

Relators Scarlett Lutz and Kayla Webster are South Carolina residents with no connection to LabCorp who filed this suit on behalf of the United States and the States of California and Illinois (collectively, the "Government"). *Id.* ¶¶ 47, 51. After investigating Relators' allegations, the Government declined to intervene against LabCorp. *Id.* ¶ 46.

II. PROCEDURAL BACKGROUND

This case was originally part of a suit Relators filed under seal more than five years ago, in February 2013, in the Western District of North Carolina. That action principally alleged liability for false claims submitted to the Government by HDL and Singulex. *See* FAC ¶ 32. As the Court may recall, HDL and Singulex were two laboratory testing companies (and LabCorp competitors) that, as the Complaint alleges, paid doctors kickbacks in order to induce referrals

for their testing services. As per the Complaint, in addition to naming HDL and Singulex as defendants in their suit about this kickback scheme, Relators sued five other defendants—former HDL executive LaTonya Mallory, the marketing company BlueWave Healthcare Consultants Inc. ("BlueWave"), BlueWave's owners Floyd Calhoun Dent and Robert Bradford Johnson, and finally LabCorp—for alleged roles in the scheme. *Id.* ¶ 38.

Relators' suit was transferred to this Court in January 2014. *Id.* ¶ 36. In September 2014, this Court severed the claims against LabCorp from the claims brought against the other defendants. *Id.* ¶ 37.

The Government intervened in the case against the other defendants. *Id.* ¶¶ 38, 41. HDL and Singulex settled before trial, in April 2015. *Id.* ¶ 39. The case against the remaining defendants proceeded to trial. *Id.* ¶¶ 43-45. Ultimately, following a jury trial, this Court entered judgment for the Government in May 2018 against defendants Johnson, Dent, and Mallory (but not BlueWave). That judgment has been appealed to the U.S. Court of Appeals for the Fourth Circuit, where the case is currently pending. *See* 4th Cir. Nos. 18-1811, 18-1812, 18-1813.

As the cases against other defendants proceeded, the federal government continued to investigate the allegations against LabCorp. FAC ¶ 46. LabCorp cooperated with the government's investigation and produced extensive documentary evidence (which Relators appear to rely upon heavily in the Complaint). In the end, the Government declined to intervene in the claims against LabCorp. *Id.* On June 26, 2018, Relators filed the Fourth Amended Complaint, which remains the operative pleading. *See* Dkt. No. 50. LabCorp now files this motion to dismiss.

III. RELATORS' THEORIES

Relators assert claims under the federal FCA, the California Insurance Fraud Prevention Act ("CIFPA"), and the Illinois Insurance Claims Fraud Prevention Act ("ICFPA"), which each

prohibit the submission of false claims for payment. Their allegations essentially consist of three theories. *See* FAC ¶ 5.

The first theory seeks to hold LabCorp liable for claims submitted by HDL and Singulex—*i.e.*, the very claims that were the subject of the settlements and trial described above. Relators contend that HDL and Singulex wrongly paid doctors' draw fees or processing-and-handling fees in order to induce the referral of their lab testing services, which were ultimately paid for by the government. According to Relators, this scheme violated the federal Anti-Kickback Statute ("AKS"), which makes it a felony to willfully pay "any remuneration . . . to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). Relators allege that HDL and Singulex violated the FCA for submitting claims that resulted from AKS violations.

Relators devote much of their Complaint to this third-party misconduct, apparently attempting to tarnish LabCorp by proximity. Indeed, *less than half* of the factual allegations contain substantive allegations about LabCorp. LabCorp is not alleged to have any involvement in the payment of the purported kickbacks, in the doctors' decisions to order services from HDL or Singulex, or in HDL's and Singulex's claims for payment. To the contrary, as Relators acknowledge, LabCorp *contacted the government* about HDL and Singulex in "early 2013," and again in "early 2014," with concerns that these "two companies [were] 'bad actors'" engaged in fraud. FAC ¶¶ 325, 327. LabCorp's efforts led in June 2014 to "OIG issu[ing] a Special Fraud Alert" in response to these requests. *Id.* ¶ 328. Nonetheless, Relators try to spin LabCorp's reporting to their advantage, contending that LabCorp's awareness of those companies' practices

equals complicity. Unsatisfied with their recovery thus far for the HDL and Singulex claims, Relators now target deeper pockets with the theory that LabCorp should be held responsible for "causing" both companies' false claims whenever a doctor ordered tests from HDL or Singulex for which the patient's blood happened to be drawn by a LabCorp phlebotomist.

Relators' second theory is that LabCorp's *own* claims resulted from AKS violations—not because LabCorp paid improper fees (as HDL and Singulex allegedly did), but rather because LabCorp purportedly used IOPs to draw patients' blood in doctors' offices. *See* FAC ¶ 5. Providing an IOP is appropriate—as the OIG has recognized for decades, *see, e.g.*, 1994 OIG Guidance—and spares patients the inconvenience of needing to later have their blood drawn elsewhere. The OIG has opined that in certain circumstances providing IOPs could possibly constitute remuneration (and thus implicate the AKS) if the IOP "performs clerical or medical functions not directly related to the collection or processing of laboratory specimens." *Id.* But Relators do not allege that LabCorp IOPs did this.

Instead, Relators contend that LabCorp's use of IOPs violated the AKS because these phlebotomists sometimes drew enough blood for all of the tests (and not just the LabCorp tests) ordered by a patient's doctor, including tests ordered from other laboratories. This practice is known as a "courtesy draw" because it permits patients to have their blood drawn only once, as a courtesy, instead of requiring a second needle stick with a possible trip to a separate testing center. In Relators' view, these courtesy draws provided to the patients amounted to criminal kickbacks to the physicians that tainted the resulting LabCorp claims, making those claims false.

Relators' third theory relatedly contends that LabCorp's claims were false because they sought payment for tests that sometimes overlapped or duplicated the tests performed by HDL and Singulex for the same patients. *See* FAC ¶ 5. Relators contend these tests were, therefore,

not "medically necessary" and, as a result, were not properly reimbursable. As the Complaint reflects, however, the doctors ordered the tests, and only then did LabCorp perform the ordered tests. *See, e.g.*, FAC ¶¶ 234, 251.

Relators seek to recover on these three theories through four different counts. Count I arises under the federal FCA, concerns claims submitted to federal health care programs such as Medicare and Medicaid, and seeks to hold LabCorp liable for either submitting or causing the submission of false claims. Count II seeks to impose FCA liability for "reverse false claims," because LabCorp did not repay funds that were purportedly received improperly as alleged in Count I. Count III asserts claims under the CIFPA, which is a California state law analogous to the FCA but that concerns claims submitted to private insurers. Finally, Count IV asserts claims under the ICFPA, which is an Illinois law like the CIFPA that similarly concerns claims submitted to private insurers. For Counts I, III, and IV, Relators contend that LabCorp both is directly liable and also is liable for conspiring with its competitors HDL and Singulex. *See* FAC ¶¶ 588, 602, 613.

APPLICABLE PLEADING STANDARDS

Under Fed. R. Civ. Proc. 12(b)(6), a court must dismiss a complaint that does not allege facts that, if "accepted as true[,] . . . 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The complaint may not rest on "'labels and conclusions,'" nor merely give a "'formulaic recitation of the elements of a cause of action,'" nor show "a sheer possibility that a defendant has acted unlawfully." *Id.* Rather, the complaint must offer sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

Moreover, because the Complaint's claims all sound in fraud, Relators must allege their claims with particularity as required by Fed. R. Civ. Proc. 9(b). *See, e.g., Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783-84 (4th Cir. 1999). To satisfy this heightened standard, the Complaint must provide particularized allegations of fraud for each of Relators' claims—with specific details on the allegedly false claims as well as the purported underlying scheme. *See, e.g., id.* Moreover, when a complaint alleges "a long chain of causal links from defendants' conduct to the eventual submission of claims," "Rule 9(b) requires relators to adequately allege the entire chain—from start to finish—to fairly show defendants caused false claims to be filed." *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017).

ARGUMENT

Although many of the Complaint's crucial allegations are demonstrably untrue, LabCorp recognizes that the non-conclusory factual allegations must be accepted at face value for purposes of this Motion. *See, e.g., Iqbal*, 556 U.S. at 678. Nonetheless, even though Relators can draw from a full trial on the HDL/Singulex kickback scheme and also appear to have access to the extensive documentary evidence that LabCorp produced to the federal government, the Complaint still fails to state a valid claim for most of its Counts. In particular, the non-kickback portion of Count I, all of Count II, all of Count III, and all of Count IV should be dismissed. Likewise, Relators' conspiracy claims should be dismissed.

I. LabCorp Does Not Certify the Medical Necessity of Tests Ordered by Doctors.

Relators' third theory, which spans all four Counts, is that LabCorp should be liable for submitting claims for services that overlapped with claims submitted by HDL and Singulex and thus were not medically necessary. This is a legally defective basis for false claims liability for LabCorp. LabCorp plays no role in determining what tests are ordered by a physician to be

performed on a patient's blood; the Complaint does not allege otherwise. As such, LabCorp does not (and is not alleged to) determine the medical necessity of the ordered tests. *See, e.g.*, *United States v. Bertram*, 900 F.3d 743, 750 (6th Cir. 2018) ("[A] laboratory generally may rely on [a] doctor's order in submitting a claim for reimbursement as medically necessary."); *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155, 158 (D.D.C. 2017) ("A laboratory cannot and is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary."). Those judgments are instead the province of the patient's doctor, and LabCorp follows a doctor's orders on which tests to run. As this Court stated during the BlueWave trial, "[y]ou cannot hold a lab liable" on a theory under which "the lab[] had to second-guess the doctors." Trial Tr. 2706:19-21 (Jan. 30, 2018).

Notably, Relators do not allege that anything was *factually* false about LabCorp's claims in question—*e.g.*, that LabCorp billed for services that were not actually provided. Instead, Relators press a theory of *legal* falsity, where the only falsity is that LabCorp's claims allegedly did not comply with a purported reimbursement rule—namely, that the services provided needed to be "medically necessary." FAC ¶ 120, 587. Such a theory can stand *only* if LabCorp falsely certified that its claims were for "medically necessary" services; without such a certification, there would be nothing false about LabCorp's claims.[3]

The necessary certification can be either explicit or implicit. *See, e.g.*, *A1 Procurement, LLC v. Thermcor, Inc.*, No. 15-cv-00015, 2017 WL 9478501, at *11 (E.D. Va. Apr. 4, 2017).[4] But Relators do not allege that LabCorp ever expressly certified the medical necessity of its

[3] This certification requirement does not apply when the only alleged falsity is a violation of the AKS. *See* 42 U.S.C. § 1320a-7b(g).
[4] All unreported cases are attached hereto in Exhibit A.

claims. Relators thus must rely on an implied certification—in other words, that a certification of medical necessity was "implicit in [LabCorp] making the claim." *Id.* But there is none present here.

The Supreme Court recently addressed the standard for implied certification in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). There, the Court held that an implied certification is present "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001. Thus, in *Escobar*, where the defendant clinic had "submitt[ed] claims for payment using payment codes that corresponded to specific counseling services," the Court held that the claims' submission implied that the counselors were properly qualified. *Id.* at 2000. As the Court explained, "[a]nyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that the clinic had complied with [these] core Massachusetts Medicaid requirements." *Id.*

But submitting a claim does not always certify the claim's compliance with billing regulations. In *U.S. ex rel. Lisitza v. Par Pharmaceutical Cos.*, 276 F. Supp. 3d 779 (N.D. Ill. 2017), for example, the court found no implied certification. There, the relator argued that pharmacies submitted false claims by supplying "an alternate form or dosage strength . . . [of] the originally prescribed drug, without regard for regulations requiring physician authorization and the dispensing of only medically necessary and economical treatments." *Id.* at 782. The court "assum[ed] violations of the 'medically necessary'" requirement but still rejected the

theory, because the claims did nothing more than request payment. *Id.* at 797. Thus, "those violations might lead to 'unauthorized billing,' but they do not, without some 'specific representation,' make the submitted claims 'false.'" *Id.*; *see also id.* at 801 (alleged noncompliance must go "directly to the truth of what was on the claim forms").

Relators' claims similarly fall short. Relators do not allege that LabCorp's claim forms made any false representations about the medical necessity of the services provided. And, contrary to the submissions at issue in *Escobar*, no one would understand LabCorp to be making any implicit representations of medical necessity when submitting a claim. As Relators concede, it is the "*physician* [who] must certify the necessity of the services." *Id.* ¶ 120 (emphasis added). Moreover, as courts have explained, "a laboratory generally may rely on that doctor's order in submitting a claim for reimbursement as medically necessary." *Bertram*, 900 F.3d at 750; *see also, e.g.*, *Groat*, 296 F. Supp. 3d at 159 ("[A] laboratory cannot and is not required to determine medical necessity, but rather is permitted to rely on the ordering physician's determination that the laboratory tests billed to Medicare are medically necessary."). [5] The OIG similarly "recognize[s] that laboratories do not and cannot . . . make medical necessity determinations." Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076, 45079 (Aug. 24, 1998). As this Court put it during the BlueWave trial, a lab does not need "to make an independent judgment" about medical necessity. Trial Tr. 2706:22 (Jan. 30, 2018).

[5] Courts have held that there are instances when a lab can be liable if the lab caused its tests to be medically unnecessary (by, for example, waiting months to perform them) or encouraged the ordering of medically unnecessary tests. *See Bertram*, 900 F.3d at 750; *Groat*, 296 F. Supp. 3d at 158. No such conduct is alleged here.

Thus, when LabCorp submits a claim, it makes no implicit representations about whether those services are medically necessary. Even if LabCorp's claims sought payment for services that were determined to be duplicative and not necessary, as Relators allege (and which LabCorp disputes), that "do[es] not, without some 'specific representation,' make the submitted claims 'false.'" *Lisitza*, 276 F. Supp. 3d at 797. Relators' claims for liability on this basis should accordingly be dismissed.

II. Relators Do Not Allege Any Proper Basis for Reverse False Claims Liability.

Relators' claim for reverse false claims liability, under § 3729(a)(1)(G) of the FCA, should also be dismissed. This claim both improperly duplicates Relators' claim for the submission of false claims and does not satisfy Rule 9(b).

A. This Claim Is Redundant of Count I and Thus Defective.

Unlike Relators' claims in Counts I, III, and IV, which require that LabCorp have submitted or caused the submission of false claims (known as "presentment" liability), Relators' claim in Count II for reverse false claims liability requires that LabCorp have wrongfully retained government funds. As this Court explained when addressing a similar theory during the BlueWave litigation, § 3729(a)(1)(G) "imposes liability on anyone who 'knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.'" *Berkeley Heartlab*, 247 F. Supp. 3d at 732. The gravamen of Relators' claim here is accordingly different from the rest of the Complaint—it is that LabCorp improperly obfuscated or avoided "an obligation to pay" the government and thus wrongly *retained* government funds, not that government funds were wrongfully *obtained*.

Yet Relators' Complaint treats these claims as almost exactly the same—with the same core facts, the same theories of fraud, and the same alleged damages. Indeed, besides reciting its different legal elements, *see* FAC ¶¶ 590-596, the Complaint's claim for reverse false claims is virtually identical to the Complaint's other claims. *See, e.g., id.* ¶ 590 ("Defendant LabCorp has received overpayments by Government healthcare programs for illegally-induced and/or medically unnecessary clinical laboratory testing that must be returned."). Relators fail to allege any conduct by LabCorp—such as the identification and receipt of an overpayment—that makes their claim in Count II for reverse false claims any different from their claim in Count I for presentment liability. Instead, Count II simply "alleges a failure to refund the false claims the government paid" as alleged in Count I. *U.S. ex rel. Ligai v. ETS-Lindgren Inc.*, No. H-112973, 2014 WL 4649885, at *13 (S.D. Tex. Sept. 16, 2014). "[T]he same set of operative facts give rise" to both claims. *U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-cv-3396, 2014 WL 2618158, at *27 (S.D. Tex. June 12, 2014).

Many courts—including this Court—have rejected such a theory of reverse false claims liability on redundancy grounds. *See, e.g.*, *Berkeley Heartlab*, 247 F. Supp. 3d at 733. As these courts have reasoned, otherwise "just about *any* traditional false statement or presentment action would give rise to a reverse false claim action." *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 97 (D.D.C. 2014); *see also, e.g., U.S. ex rel. Scollick v. Narula*, 215 F. Supp. 3d 26, 41-42 (D.D.C. 2016); *U.S. ex rel. Petratos v. Genentech, Inc.*, 141 F. Supp. 3d 311, 322 (D.N.J. 2015), *aff'd on other grounds*, 855 F.3d 481 (3d Cir. 2017); *U.S. ex rel. Davern v. Hoovestol, Inc.*, No. 11-CV-6630 CJS, 2015 WL 6872427, at *9 (W.D.N.Y. Nov. 9, 2015); *U.S. ex rel. Besancon v. Uchicago Argonne*, LLC, No. 12 C 7309, 2014 WL 4783056, at *4 (N.D. Ill. Sept. 24, 2014); *Ligai*, 2014 WL 4649885, at *13; *Ruscher*, 2014 WL 2618158, at *28; *U.S. ex rel.*

Sobek v. Education Management, LLC, No. 10-131, 2013 WL 2404082, at *29 (W.D. Pa. May 31, 2013); *United States v. HCA Health Servs. of Okla., Inc.*, No. 3:09-CV-0992, 2011 WL 4590791, at *8 (N.D. Tex. Sept. 30, 2011); *U.S. ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 514–15 (E.D. Pa. 2010); *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 338-39 (S.D.N.Y. 2004). Here as well, because it does not stand apart from Count I, Count II should be dismissed. Relators allege simply that LabCorp should have repaid the funds that it received in connection with Count I—which is not a proper basis of liability for reverse false claims.

B. This Claim Is Not Alleged with the Particularity Required By Rule 9(b).

Moreover, separate from its redundancy, Count II should also be dismissed for its failure to satisfy Rule 9(b). With a traditional FCA claim (such as Count I) that focuses on false claims for payment, Rule 9(b) generally requires a relator to allege the false claims and fraudulent scheme with particularity. *See Harrison*, 176 F.3d at 783-84. Reverse false claims liability, in contrast, concerns a defendant's obligation to repay funds, and Rule 9(b)'s focus shifts accordingly. A relator must instead plead particularized "facts as to the time, place, [and] substance of *any retained overpayments*" from the federal government. *Taul v. Nagel Enters., Inc.*, No. 14-cv-0061-VEH, 2017 WL 432460, at *13 (N.D. Ala. Feb. 1, 2017) (emphasis added). A relator also must allege "details about the source of the alleged [repayment] obligation" and "the parameters of that obligation, such as what trigger[ed] the duty to repay and what sort of repayment it require[d]." *Pencheng Si*, 71 F. Supp. 3d at 96; *see also Davern*, 2015 WL 6872427, at *9 (dismissing reverse false claims claim in part because complaint "fail[ed] to identify any instance in which the Government requested or demanded that [the defendant] repay money").

The Complaint fails to provide any of these details. It does not allege "the time, place or substance of any retained overpayments" from the federal government." *Taul*, 2017 WL 432460,

at *13. Nor does the Complaint allege any details for LabCorp's purported obligation to repay such supposed overpayments. Relators instead simply cite a general legal obligation to "return Government healthcare program overpayments within 60 days of identification." FAC ¶ 595. That allegation is merely a legal conclusion that adds little under Rule 9(b). The Complaint does not allege when LabCorp supposedly identified these purported "overpayments" (so as to start the purported 60-day clock), when these "overpayments" even occurred, or even what these "overpayments" were. For this reason as well, then, in addition to its redundancy to Count I, Relators' reverse false claims count should be dismissed in full.

III. Relators Lack Standing for Their State-Law Claims, Which Also Fail Rule 9(b).

Relators' two state-law claims, arising under California law (Count III) and Illinois law (Count IV) should be dismissed as well. As noted above, neither of these counts concerns claims for government payment. Instead, Relators contend that LabCorp should be liable for improper claims submitted to private insurers. But Relators lack standing to recover for such injuries. In addition, Relators do not allege these state-law claims with the specificity required by Rule 9(b).

A. Relators Lack Standing for Their State-Law Claims.

The CIFPA and ICFPA are *qui tam* statutes like the federal FCA, but with different rules of standing. Whereas the federal FCA permits "[a] *person* [to] bring a civil action" on the government's behalf, 31 U.S.C. § 3730(b)(1) (emphasis added), the CIFPA and ICFPA each confer *qui tam* standing upon only "*interested* persons." Cal. Ins. Code § 1871.7(e)(1) (emphasis added); *accord* 740 Ill. Comp. Stat. Ann. 92/15(a). "The ICFPA was modeled after the California statute and," at least according to an Illinois court, "the language of the two statutes is substantively identical." *State ex rel. Zolna-Pitts v. ATI Holdings, Inc.*, No. 12CH27483, 2013 WL 3779568, at *3 (Ill. Cir. Ct. June 18, 2013).

While the case law construing the meaning of "interested persons" is sparse, California courts have construed—including before the 1993 enactment of CIFPA—the term "interested person" in other statutes to mean (based on "long established legislative precedents") "a person having a *direct, and not a merely consequential, interest* in the litigation." *Associated Boat Indus. of N. Cal. v. Marshall*, 230 P.2d 379, 380 (Cal. Ct. App. 1951) (emphasis added); *see also, e.g., Torres v. City of Yorba Linda*, 17 Cal. Rptr. 2d 400, 403 (Cal. Ct. App. 1993) (noting that the term "any interested person" has been "narrowly construed" under California law). Illinois case law has similarly interpreted the term to require that the alleged fraud have "affected or involved" the relator. *ATI Holdings*, 2013 WL 3779568, at *2.

Here, however, Relators do not allege that they have any interest in their state-law claims beyond their potential share of damages. *See* FAC ¶ 607(B) (seeking 30-50% of damages for the CILPA claim); ¶ 618(B) (seeking 30-40% of damages for the ICFPA claim).) They do not allege having ever worked for LabCorp. Nor do they allege having ever worked or lived in California or Illinois. They also do not allege *any* connection to any private insurer in either state—not even as policyholders or shareholders. *Id.* ¶¶ 47-54. Rather, Relators simply seek to recover a portion of any judgment entered against LabCorp. That does not make them "interested persons" with *qui tam* standing under California and Illinois law, and Counts III and IV should accordingly be dismissed.

B. Relators Do Not Allege Their State-Law Claims with the Particularity Required By Rule 9(b).

Relators' CIFPA and ICFPA claims should also be dismissed for not being pled with adequate specificity. Both claims are subject to Rule 9(b). *See Maa v. Ostroff*, No. 12-CV-00200-JCS, 2013 WL 1703377, at *21 (N.D. Cal. Apr. 19, 2013) (CIFPA); *U.S. ex rel. Zverev v. USA Vein Clinics of Chicago, LLC*, 244 F. Supp. 3d 737, 743 n.2 (N.D. Ill. 2017) (ICFPA). As a

result, Relators must plead every element of both claims with particularity and cannot rest on "mere conjecture" for "an essential element" of liability. *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456–57 (4th Cir. 2013) (citing *U.S. ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1313 (11th Cir. 2002)). Relators also cannot rely on allegations made on information and belief, unless the matters at issue "are particularly within the defendants' knowledge." *Breeden v. Richmond Community College*, 171 F.R.D. 189, 197 (M.D.N.C. 1997) (internal citations omitted); *see also, e.g.*, *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 728 (10th Cir. 2006); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997); *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1279 & n.3 (D.C. Cir. 1994); *Degraw v. Wike*, No. 2:10CV435, 2011 WL 3268578, at *2 (E.D. Va. May 9, 2011); *U.S. ex rel. Doe v. CVS Corp.*, No. CIV. 2:98-2764-12, 1999 WL 33912815, at *5 (D.S.C. June 14, 1999).[6] Nor does Rule 9(b) permit a relator "merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted . . . ." *Takeda*, 707 F.3d at 456 (internal citations omitted).

The Complaint, however, suffers from exactly these flaws for two crucial CIFPA and ICFPA elements. First, the Complaint fails to identify a single false claim that LabCorp actually submitted or caused to be submitted to a California or Illinois private insurer. Second, the Complaint fails to identify any specific private insurance policies that were purportedly breached by the claims in question. Each of these pleading gaps independently requires dismissal.

[6] For such matters "particularly within the defendants' knowledge" that are alleged on information and belief, Relators must allege the facts "upon which the[ir] belief is founded." *Breeden*, 171 F.R.D. at 197.

1. Relators Fail to Identify a Single False Claim Submitted to a California or Illinois Private Insurer.

Much like with the federal FCA, the submission of a false claim is an essential element of liability under the CIFPA and ICFPA. *See People ex rel. Gov't Employees Ins. Co. v. Cruz*, 244 Cal. App. 4th 1184, 1193 (Cal. Ct. App. 2016), *reh'g denied* (Feb. 17, 2016) (CIFPA);[7] *United States v. A Plus Physicians Billing Serv., Inc.*, No. 13 C 7733, 2015 WL 8780548, at *3 (N.D. Ill. Dec. 15, 2015) (ICFPA). Instead of the FCA's requirement of a false claim submitted to the government, however, the CIFPA and ICFPA require false claims that were submitted to private insurers—which is the two Acts' main difference from the FCA.

The Complaint, however, does not identify a single purportedly false claim submitted to a California or Illinois private insurer. Instead, to allege the necessary connection to those two states, "Relators state *upon information and belief* that HDL, Singulex, and LabCorp exercised the same fraudulent scheme as described herein against private insurers in California and Illinois." FAC ¶ 564 (emphasis added). But this "information and belief" allegation holds no weight under Rule 9(b); this information is not particularly within LabCorp's knowledge, and Relators do not allege the basis for their belief. *See, e.g., Breeden*, 171 F.R.D. at 197.

Relators also allege that HDL, Singulex, and LabCorp "submitted [false] claims for payment to private insurers in California and Illinois." FAC ¶¶ 565, 566. But this is conclusory boilerplate not supported by particularized details. The complaint alleges only two claims submitted to a private insurer: one by HDL, one by Singulex, *nothing* by LabCorp, and *nothing* with a connection to California and Illinois. *See id.* ¶ 536, Exs. B-C. Such limited allegations

[7] This case concerns California Penal Code § 550, which is actionable under the CIFPA. *See* Cal. Ins. Code § 1871.7(b).

cannot carry Relators' Rule 9(b) burden for their state-law claims. *See, e.g.*, *Takeda*, 707 F.3d at 456.

Nor can Relators carry this burden through general allegations about LabCorp's connections to California and Illinois. *See, e.g.*, FAC ¶ 2 (LabCorp serves patients who are residents of California and Illinois and insured by private insurers); *id.* ¶ 80 (LabCorp does business with private insurers in California and Illinois). These general allegations neither describe a fraud (not even close), nor connect LabCorp's California and Illinois operations to the specific allegations of false claims.[8] Under Rule 9(b), it is not enough that LabCorp's purported conduct "*could* have led" to the submission of false claims to private insurers with clients in California or Illinois. *Takeda*, 707 F.3d at 457. Rather, Relators "must allege with particularity that specific false claims actually were presented" in California and Illinois. *Id.* They have not done so.

This omission may not come as a surprise. This Court granted summary judgment against these same Relators' CIFPA and ICFPA claims in the BlueWave litigation because Relators "submitted no evidence showing that HDL or Singulex submitted (or were reimbursed for) claims to private insurers with clients in California or Illinois in violation of either state's insurance statutes." *United States v. Berkeley Heartlab Inc.*, No. 9:11-CV-1593-RMG, 2017 WL 3773276, at *4 (D.S.C. Aug. 29, 2017). Indeed, there, "Relators did not [even] argue in their brief that they have such evidence." *Id.* The Complaint suggests they likewise have no support for their claim against LabCorp.

[8] Relatedly, there is no allegation that LabCorp drew the specimens for the two alleged claims submitted by HDL and Singulex to private insurers (in unknown locations). *See Haley v. Corcoran*, 659 F. Supp. 2d 714, 721 (D. Md. 2009) (internal citations omitted) ("Conclusory assertions that . . . defendants are guilty because of their association with others" do not satisfy Rule 9(b).).

Finally, Relators cannot side-step their obligation to plead state-level fraud with particularity by alleging a "nationwide" scheme. FAC ¶ 513. For one thing, this allegation is made "upon information and belief" and thus should be ignored under Rule 9(b), because it does not concern facts known only to LabCorp, and Relators also do not allege the basis for their belief. *See, e.g.*, *Breeden*, 171 F.R.D. at 197. Nor does the Complaint even allege that LabCorp had uniform practices across the country, whether for LabCorp's own claims or for HDL and Singulex. *Cf.* FAC ¶ 60 (noting LabCorp's different regional divisions). Indeed, the first "company-wide" LabCorp policy alleged in the Complaint "direct[ed] the cessation of HDL and Singulex draws," after LabCorp had contacted the OIG with its concerns about both companies' practices and received the OIG's Special Fraud Alert in response. *Id.* ¶ 329.

In short, Relators cannot simply allege that because the purported government fraud may have occurred in South Carolina, it must also have been occurring with private insurers in California and Illinois. Rule 9(b) prohibits this presumption, which is fatal to Counts III and IV.

2. Relators Fail to Identify Any Private Insurance Policies That Were Purportedly Breached.

The Complaint also lacks specificity regarding the private insurance policies purportedly breached. The Complaint merely presumes—again, on "information and belief"—that "private healthcare insurance companies in California and Illinois require the same conditions of payment and prohibitions on unnecessary medical testing found in the Medicare and Medicaid programs." FAC ¶ 178; *see also id.* ¶ 155 ("Upon information and belief, the contracts for those private insurers whose patients are drawn into the LabCorp, HDL, and Singulex referral scheme mirror the Medicare and Medicaid requirements by mandating that laboratory testing billed to private insurers is not the result of an illegal inducement, and is medically necessary."). Rule 9(b) does

not permit this inference that private insurance policies must mirror the "conditions of payment and prohibitions" for Medicare and Medicaid claims. *Id.* ¶ 178.

Rule 9(b) instead requires the substance of the insurance policies to be alleged with particularity—because such contracts cannot be presumed identical. Thus, in *United States v. Triple Canopy, Inc.*, the Fourth Circuit held that the relators "cannot state a claim by doing 'nothing more than simply presum[ing]' that [defendant] submitted false claims" under five different contracts based on specific allegations as to one. 775 F.3d 628, 640 (4th Cir. 2015), *judgment vacated on other grounds sub nom. Triple Canopy, Inc. v. U.S. ex rel. Badr*, 136 S. Ct. 2504 (2016), *and opinion reinstated in part*, 857 F.3d 174 (4th Cir. 2017). Similarly, in *U.S. ex rel. Thomas v. Siemens AG*, the relator alleged a theory of liability across 21 different contracts but alleged only 4 of them with particularity; applying Rule 9(b), the court rejected the relator's claims for the other 17 contracts, because "nothing more than conjecture" supported the contracts all being similarly problematic. 708 F. Supp. 2d 505, 515 (E.D. Pa. 2010).

Here, although the Complaint details the alleged payment policies of the government-funded insurance programs at issue, *see, e.g.*, FAC ¶¶ 104-154, the Complaint says virtually nothing about the private insurance policies implicated by Relators' CIFPA and ICFPA claims. Aside from a handful of conclusory "information and belief" claims—which cannot help Relators under Rule 9(b), *see, e.g.*, *Breeden*, 171 F.R.D. at 197—the Complaint is silent about the policies' coverage rules and payment conditions. *Id.* ¶¶ 155, 178, 538. These "baseless assumption[s] unsupported by factual allegations" are insufficient to sustain Relators' state-law claims. *Siemens*, 708 F. Supp. 2d at 515. For this reason as well, Counts III and IV should be dismissed.

IV. Relators Fail to Allege Essential Elements of Their Conspiracy Claims.

Finally, Relators' claims that LabCorp conspired with HDL and Singulex should also be dismissed. To state a claim for conspiracy liability, the Complaint must allege (among other things) "(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim reimbursed by the government and (2) at least one act performed in furtherance of that agreement." *U.S. ex rel. DeCesare v. Americare In Home Nursing*, 757 F. Supp. 2d 573, 584 (E.D. Va. 2010). Moreover, the Complaint must allege that the conspirators "shared a specific intent to defraud the Government." *Id.* The Complaint does not allege these necessary elements with the particularity required by Rule 9(b). There is no allegation that LabCorp formed *any* agreement with HDL or Singulex regarding phlebotomy services, much less any agreement concerning the submission of false claims. *Cf. United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487 (D.S.C. 2016) (declining to dismiss conspiracy claim because of sales agreement between defendants in BlueWave litigation). Nor does the Complaint plausibly allege that LabCorp, HDL, and Singulex "shared a specific intent to defraud the Government." *DeCesare*, 757 F. Supp. 2d at 584.

If anything, LabCorp's alleged actions actually undermine Relators' conspiracy claims. HDL and Singulex are both LabCorp competitors. Far from working with them to defraud the Government, LabCorp reported their conduct to the OIG. LabCorp worked to educate doctors and clinics on why HDL's and Singulex's practices were not appropriate, and LabCorp twice sought the fraud alert that resulted in HDL and Singulex changing their business practices. *See, e.g.*, FAC ¶¶ 16, 352. These actions contradict any suggestion that LabCorp was somehow conspiring with HDL and Singulex.

Nor can Relators' conspiracy theory rest on their allegations that LabCorp considered acquiring HDL. As the Complaint itself acknowledges, LabCorp never entered into any such

transaction and, instead, engaged only in preliminary high-level discussions. *See* FAC ¶ 422. This falls far short of Relators' burden to plead particularized allegations establishing an "unlawful agreement" between LabCorp and HDL. Relators' conspiracy claims should be dismissed out of hand.

CONCLUSION

The Complaint's theories of liability will not withstand scrutiny and lack a factual basis. While LabCorp recognizes that it must accept well-pled allegations as true for purposes of this Motion, the Complaint's claims are nonetheless largely implausible and/or legally defective and should be dismissed at this stage. Count I should be dismissed for any non-kickback or conspiracy theory of liability. Counts II, III, and IV should be dismissed in full. In addition, these claims should all be dismissed with prejudice, because their legal defects cannot be cured with an amended pleading. *See, e.g.*, *Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 630-31 (4th Cir. 2008). Finally, LabCorp wishes to advise the Court that it believes oral argument would be particularly helpful with this Motion, given the complexity of Relators' factual allegations and the underlying legal issues.[9]

[signature page to follow]

[9] A "motion for partial dismissal postpones the deadline for filing an answer to all claims, not just those subject to the motion." *Maass v. Lee*, 189 F. Supp. 3d 581, 587 (E.D. Va. 2016); *see also, e.g.*, *Johnson v. Pope*, No. 7:13-CV-78-BO, 2013 WL 6500752, at *3 (E.D.N.C. Dec. 11, 2013).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing ***Motion to Dismiss Fourth Amended Qui Tam Complaint and Memorandum of Law in Support of Motion to Dismiss Fourth Amended Qui Tam Complaint*** was filed through the Court's ECF system on October 10, 2018, notice of which will be sent electronically to all counsel of record.

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